REMARKS

Reconsideration of the present application is respectfully requested in view of the above amendments and the following remarks. Claims 1-13 are pending in the application; claims 1-7 and 13 are currently under examination, and claims 8-12 are withdrawn. Without acquiescence to the rejection, claims 1, 6, and 7 are amended to more particularly point out and distinctly claim certain embodiments of Applicants' invention. No new matter has been added by the amendments. Support for the amendments can be found in the specification as originally filed, for example, at page 32, line 26 to page 33, line 1; page 33, lines 6-14; page 34, lines 6-7.

PRIORITY CLAIM

Applicants kindly thank the Examiner for expressly acknowledging Applicants' priority claim to Korean Application No. 10-2003-0080299. Applicants submit herewith a copy of Form PCT/IB/304 that notes January 25, 2005, as the date of receipt of the priority document by the International Bureau. Applicants believe this document shows the requirement to provide the priority document under 35 U.S.C. § 119(b) has been met. Applicants will supply a copy of this document upon request. Applicants respectfully request the Examiner to accord the instant claims the priority filing date of 11/13/2003.

CLAIM OBJECTIONS

The Examiner objected to claim 6 for allegedly failing to further limit the subject matter of the claim from which it depends.

Applicants respectfully disagree and submit that claim 6 further limits the subject matter of claim 5. In this regard, Applicants are sincerely confused by Examiner's assertion that the recitation "derived" opens the claim to any aglycosylated Fc fragment, such as an IgG1 Fc fragment, especially when claim 6 clearly refers to the polypeptide of claim 5, which is an IgG4 Fc fragment. Nonetheless, without acquiescence, claim 6 as amended recites "wherein the aglycosylated IgG4 Fc fragment [of claim 5] is human-derived," which Applicants believe to more clearly limit the aglycosylated IgG4 Fc fragment of claim 5 to that derived from humans, as opposed to any other animal.

Applicants, thus, respectfully request withdrawal of this objection.

REJECTIONS UNDER 35 U.S.C. § 102

A. The Examiner rejected claims rejected claims 1-7 and 13 under 35 U.S.C. § 102(b) for alleged lack of novelty over Cox *et al.* (WO 2001/03737). The Examiner asserts that Cox *et al.* teach an Fc fragment such as IgG4 that is linked to various therapeutic factors, such as G-CSF.

B. The Examiner rejected claims rejected claims 1-7 and 13 under 35 U.S.C. § 102(b) for alleged lack of novelty over Nakamura *et al.* (EP 0227110). The Examiner asserts that Nakamura *et al.* teach a pharmaceutical composition comprising recombinant IgG Fc in a carrier such as PBS.

C. The Examiner rejected claims rejected claims 1-7 and 13 under 35 U.S.C. § 102(b) for alleged lack of novelty over Jendenburg *et al.* (*J. Immunol. Method.* 201:25-34, 1997). The Examiner asserts that Jendenberg *et al.* teach a recombinant Fc fragment from human IgG made in *E. coli,* and further asserts that the intended use of a drug carrier does not carry patentable weight.

Applicants respectfully traverse each of these rejections, detailed as A through C above, and submit that the instant claims satisfy the requirements of novelty over each of the cited references. Embodiments of the instant claims relate, in pertinent part, to an Fc fragment as a drug carrier, which is an IgG Fc, a combination thereof or a hybrid thereof, wherein the Fc fragment is covalently linked to a drug through a non-peptide linker, and compositions thereof.

None of the cited references disclose each feature of the instant claims. For instance, none of the cited references disclose an Fc fragment that is covalently linked to a drug through a non-peptide linker, nor do they disclose a pharmaceutical composition thereof.

Cox *et al.* fail to disclose an Fc fragment that is covalently linked to a drug through a non-peptide linker. To the contrary, Cox *et al.*, at best, merely discuss fusion or chimeric proteins, and, in this context, are limited to the use of peptide linkers. By failing to teach or suggest the use of covalent, non-peptide linkers to attach an Fc fragment to a drug, as presently claimed, Cox *et al.* fail to anticipate the instant claims.

Nakamura *et al.* fail to disclose an Fc fragment that is covalently linked to a drug through a non-peptide linker. Indeed, Applicants submit that this reference is entirely silent as to the use of use of covalent, non-peptide linkers to attach an Fc fragment to a drug, as presently claimed. Absent evidence by the Examiner to the contrary, Applicants submit that Nakamura *et al.* fail to disclose a compound or composition of matter as presently claimed, and, therefore, fail to anticipate the instant claims.

Jendenberg *et al.* fail to disclose an Fc fragment that is covalently linked to a drug through a non-peptide linker. Similar to Nakamura *et al.*, Jendenberg *et al.* are also entirely silent as to the use of covalent, non-peptide linkers to attach an Fc fragment to a drug, as presently claimed. Since Jendenburg *et al.* fail to disclose a compound or composition of matter as presently claimed, then this reference fails to anticipate the instant claims.

In view of the deficiencies of the cited references, Applicants submit that the instant claims satisfy the requirements of novelty over each of these references, and respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. §102(b).

DOUBLE PATENTING REJECTIONS

A. The Examiner provisionally rejected claims 1-7 and 13 for alleged obviousness-type double patenting over claims 1-13 of co-pending U.S. Application No. 10/535,231.

B. The Examiner provisionally rejected claims 1-7 and 13 for alleged obviousness-type double patenting over claims 1-19 and 27-44 of co-pending U.S. Application No. 10/535,232.

The Examiner agrees that the allegedly conflicting claims are not identical in scope, but asserts that they are not patentably distinct from each other, asserting that they are drawn to nearly the same type of IgG Fc fragment-containing compositions.

Applicants traverse these rejections. Nonetheless, since these rejections are provisional, Applicants will address the rejections upon allowance of a claim set in either this application, or the above-noted co-pending applications.

Applicants believe that all of the claims in the application are allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Respectfully submitted,

SEED Intellectual Property Law Group PLLC

/William T. Christiansen/
William T. Christiansen, Ph.D.
Registration No. 44,614

WTC:MER:jto

Enclosure:
Copy of Form PCT/IB/304

701 Fifth Avenue, Suite 5400
Seattle, Washington 98104
Phone: (206) 622-4900
Fax: (206) 682-6031

1290837_1.DOC